activities related to the regulation of OTC monograph drug products, including provisions of section 505G of the FD&C Act that facilitate innovation and make it easier for FDA to better respond to safety issues when they emerge. We provide information regarding the OMUFA program on our website at *https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa.*

We developed Form FDA 5009, *Over-The-Counter Monograph User Fee Cover Sheet,* (available at *www.fda.gov/about-fda/reports-manuals-forms/forms,* Search for Form FDA 5009) to facilitate the submission of OMUFA fees and to more efficiently administer the OMUFA program. Form FDA 5009 provides FDA with necessary information to determine the total user fee payment amount required and to help the Agency track payments. Respondents to this collection are qualifying finished dosage form manufacturers of OTC monograph drugs and submitters of qualifying OMORs submitted under section 505G(b)(5) of the FD&C Act.

We estimate the burden of collection of information as follows:

TABLE 3—ESTIMATED ANNUAL OMUFA REPORTING BURDEN [1]

Form FDA 5009—OMUFA cover sheet	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Submission associated with facility fees	1,184	1	1,184	*0.5	592
Submission associated with fees for qualifying OMORs	5	1	5	*0.5	2.5
Total					594.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
* 30 minutes.

Based on data from our electronic Drug Registration and Listing System, we estimate that there will be 1,184 respondents who will provide information in conjunction with facility fee payments annually. In addition, consistent with the Over-the-Counter Monograph User Program Performance Goals and Procedures commitment letter (available at *https://www.fda.gov/media/106407/download*), we estimate submitters will provide the user fee information using Form FDA 5009 in conjunction with an average of five qualifying OMORs annually. We assume the user fee-related submissions will require an average of 30 minutes to prepare, for a total of 594.5 hours annually.

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19502 Filed 9–8–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0528]

Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drug Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled ''Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drug Products.'' This draft guidance is intended to assist industry in providing information in labeling about the quantities at which sodium, potassium, and phosphorus as constituents of active or inactive drug ingredients are present in human over-the-counter (OTC) and prescription drug products.

DATES: Submit either electronic or written comments on the draft guidance by November 8, 2022 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked, and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0528 for ''Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drugs.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential

information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov*. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Dat Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3334, Silver Spring, MD 20993, 240–402–8926, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drugs Products.'' This draft guidance focuses on sodium, potassium, and phosphorus when present as constituents of active or inactive drug product ingredients (*e.g.,* sodium as a constituent of the inactive ingredient anhydrous trisodium citrate, phosphorus as a constituent of the inactive ingredient dibasic calcium phosphate, or sodium as a constituent of the active ingredient naproxen sodium).

Sodium, potassium, and phosphorus are often present in drug products as constituents of active or inactive ingredients. The amounts of these constituents can vary among drug products, including drugs with the same active ingredient, depending on factors such as the manufacturer, formulation, and dosage form. For example, the amount of sodium, potassium, or phosphorus may differ between a reference listed drug and a generic version of the drug, or the amount may vary among different generic versions of the same drug.

This draft guidance restates the legal requirements set forth in current regulations for the quantitative labeling of sodium and potassium for OTC products intended for oral ingestion. There is no current regulation requiring quantitative information specifically for sodium or potassium in prescription drugs. However, this draft guidance recommends that manufacturers of OTC and prescription drug products include quantitative information for sodium, potassium, and phosphorus (when present above threshold levels described in the draft guidance) in the product's labeling to assist healthcare providers and patients.

Healthcare providers generally recommend that patients with certain clinical conditions such as heart failure, hypertension, or chronic kidney disease, restrict dietary intake of sodium, potassium, or phosphorus. Including information about the quantities of these constituents in drug product labeling would allow healthcare providers and patients to account for the amounts of these constituents present in a patient's daily drug regimen when determining an individual's total daily intake. Quantifying these constituents in drug product labeling as recommended in this draft guidance may allow healthcare providers and patients to select drug products with lower amounts of these constituents when necessary if such alternatives are available.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Quantitative Labeling of Sodium, Potassium, and Phosphorus for Human Over-the-Counter and Prescription Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to proposed collections of information described in FDA's 60-day notice requesting public comment on the proposed collection of information entitled, ''Agency Information Collection Activities; Proposed Collection; Comment Request; General Drug Labeling Provisions and Over-the-Counter Monograph Drug User Fee Submissions.'' The proposed collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520). As required by the PRA, FDA has published an analysis of these information collection provisions elsewhere in this edition of the **Federal Register** and will submit them for OMB approval following the period for public comment.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in certain sections of 21 CFR part 201 have been approved under OMB control number 0910–0572; the collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001; and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/*

vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents or *https://www.regulations.gov*.

Dated: September 2, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–19501 Filed 9–8–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–1263]

Submitting Documents Using Real-World Data and Real-World Evidence to the Food and Drug Administration for Drug and Biological Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.'' To facilitate FDA's internal tracking of submissions to the Agency that include real-world data (RWD) and real-world evidence (RWE), this guidance encourages sponsors and applicants to identify in their submission cover letters certain uses of RWD/RWE. This guidance does not address FDA's substantive review of the RWD/RWE submitted as part of the Agency's standard review process. This guidance finalizes the draft guidance entitled ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drugs and Biologics'' issued on May 9, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on September 9, 2022.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2019–D–1263 for ''Submitting Documents Using Real-World Data and Real-World Evidence to FDA for Drug and Biological Products.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Raymond Chiang, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2232, Silver Spring, MD 20993–0002, 301–796–1940; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled